REMARKS

Claims 1, 3-7, 10, and 12-15 are pending in the application. Claims 1, 3-7, 10, and 12-15 are rejected. No claims are allowed. Claims 1, 3-7, and 14 have been cancelled. Claims 10 and 15 have been amended. New claims 22-31 have been added. Upon entry of this response, claims 10, 12-13, 15, and 22-31 will be presented for examination.

Applicants respectfully request entry of the above amendments to the claims. Claim 10 have been amended to recite the limitation that the composition is topically applied to aged skin in an amount effective to provide an anti-ageing effect. Newly added claims 27-28 are specific to stimulating the growth and/or metabolism of human fibroblasts. Newly added claims 29-30 are specific to protection of human fibroblasts from UV-A effects, protection of human keratinocytes from UV-B effects, and inhibition of melanin synthesis. Support for the amendments can be found at least at page 6, lines 2-8, and at the Examples on pages 29-37 of the substitute specification. Newly added claims 22-26 have been added, support for which can be found at least at page 6, lines 24-28 and at page 1, lines 5-9 of the substitute specification as originally filed. Newly added claim 31 is specific to application of the composition to skin showing signs of ageing, support for which can be found at least at page 8, lines 14-24 of the substitute specification.

No new matter has been added by this amendment.

Reconsideration of the rejections and allowance of claims 10, 12-13, 15, and 22-31 in view of the following remarks are respectfully requested. As will be discussed below, these claims provide for a method for treatment of aged skin comprising topically applying to the aged skin of a patient in need thereof a composition comprising a plant extract from a source of *Buchholzia coriacea* in an amount effective to provide an anti-ageing effect. The plant extract is obtained by extracting at least a portion of the *Buchholzia coriacea* plant with water to form a solution. In some embodiments, the anti-ageing effect is selected from inhibiting the synthesis of melanin, decreasing the effects of skin pigmentation, stimulating the growth and/or metabolism of human fibroblasts, providing a revitalizing or rejuvenating effect on stressed or tired skin, promoting the repair of aged and/or photoaged skin, providing an appeasing and anti-irritating effect against oxidative stress and pollutants, providing a protease inhibition effect, providing an

antioxidant effect, and/or protecting against UV or IR radiation. The cited references do not contemplate such a method of treatment.

Claim Rejections – 35 U.S.C. § 102 and 35 U.S.C. § 103

Claims 1, 3, 4, 10 and 12-15 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the admitted state of the art. According to the Office Action, the prior art teaches extracts of *Buchholzia coriacea*.

Claims 1, 3-7, 10, 12-15, and 17-21 have been rejected under 35 U.S.C. §103 (a) as allegedly being obvious over the admitted state of the art in view of Doi et al. (JP 411322630A).

According to the Office Action, a composition comprising a fruit extract from *Buchholzia coriacea* has been effectively used in the prior art to treat earaches and back pain via topical application of such a fruit extract thereto, which anticipates and renders obvious, the claimed invention. (Office Action at page 4).

Applicants respectfully traverse these bases for rejection.

It has long been the law that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, for an anticipation rejection to be proper, the reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *See In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) ("But disclosure of each element is not quite enough – this court has long held that '[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim.*'") (quoting *Connell v. Sears, Roebuck & Co.,* 722 F.2d 1542, 1548 (Fed. Cir. 1983) (emphasis in original).

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467

(1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

Claim 1

Claims 1 and 3-7 have been cancelled, thus rendering their rejections moot.

Claim 10

Claim 10, as amended is directed toward a method for treatment of aged skin comprising topically administering to the aged skin of a patient in need thereof a composition comprising: a plant extract from a source of *Buchholzia coriacea* in an amount effective to provide an anti-ageing effect. The plant extract is obtained by extracting at least a portion of the *Buchholzia coriacea* plant with water to form a solution.

According to the Office Action, a water extract solution from the seeds of *Buchholzia coriacea* has been used to treat earaches via topical application thereto. (Office Action at pages 2-3). Additionally, the Office Action states that a composition comprising a fruit extract from *Buchholzia coriacea* has been used to treat back pain via topically massaging such a fruit extract thereto. (*Id.*). The Office Action submits that both earaches and back pain are commonly associated with skin inflammation. (*Id.*)

Applicants' invention, however, is not directed toward the use of *Buchholzia coriacea* extract as a treatment for earaches or back pain or skin inflammation. Rather, Applicants' invention is directed toward the use of *Buchholzia coriacea* extract for treatment of aged human skin. The invention provides that the anti-ageing effect is selected from inhibiting the synthesis of melanin, decreasing the effects of skin pigmentation, stimulating the growth and/or metabolism of human fibroblasts, providing a revitalizing or rejuvenating effect on stressed or tired skin, promoting the repair of aged and/or photoaged skin, providing an appeasing and anti-irritating effect against oxidative stress and pollutants, providing a protease inhibition effect, providing an antioxidant effect, and/or protecting against UV or IR radiation. In particular embodiments, provided are the anti-ageing effects of stimulating the growth and/or metabolism of human fibroblasts, and inhibiting the effects of UV radiation through the protection of human fibroblasts from UV-A effects, protection of human keratinocytes from UV-B effects, and inhibition of melanin synthesis. Another embodiment specifies that the composition is topically applied to skin showing signs of ageing.

The Office Action alleges that that the claimed functional effects (i.e., anti-ageing) would be inherent upon topical application to the skin. (Office Action at page 5). The Office Action's allegation relies on a mere possibility that application of *Buchholzia coriacea* extract to the skin would produce anti-ageing effects. The cited art is devoid of any such teaching. Moreover, with respect to claims 22-31, the art further fails to provide any suggestion or teaching that *Buchholzia coriacea* extract inhibits the synthesis of melanin, decreases the effects of skin pigmentation, stimulates the growth and/or metabolism of human fibroblasts, provides a revitalizing or rejuvenating effect on stressed or tired skin, promotes the repair of aged and/or photoaged skin, provides an appeasing and anti-irritating effect against oxidative stress and pollutants, provides a protease inhibition effect, provides an antioxidant effect, and/or protects against UV or IR radiation. In addition, with respect to claim 10, the prior art is devoid of any showing that the composition is topically applied to aged skin. Therefore, the Examiner's allegation regarding the inherent properties of *Buchholzia coriacea* extract is misguided, and is an incorrect interpretation of the law.

The Federal Circuit held that "to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the

reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). The prior art is devoid of any teaching or suggestion that Applicants' invention would produce anti-ageing effects. Specifically, the art fails to teach or suggest stimulating the growth and/or metabolism or human fibroblasts, protecting human fibroblasts from UV-A effects, protecting human keratinocytes from UV-B effects, and inhibiting melanin synthesis as observed by Applicants' invention. Thus, the allegation that any such anti-ageing effects would be inherent upon topical application to the skin is relying upon probabilities and possibilities and is not permitted.

In addition, the Federal Circuit also held that "new uses of old products or processes are indeed patentable subject matter." *Nicholas v. Perricone, M.D.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005). In this case, where Perricone claimed a new use of a composition disclosed by Pereira, the Court found that "the district court's inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent." *Id.* at 1379. The court went on to explain that "only by dismissing the explicit language of Dr. Perricone's claimed method: 'applying to the skin sunburn'," can one argue that Pereira discloses Perricone's invention; the Court found this reasoning to be misguided and vacated the district court's summary judgment of non-infringement. *Id.* The Court found that the treatment of skin sunburn was not analogous to preventing sunburn, and, therefore, a topical composition for treating skin sunburn was a patentable new use of an old product. *Id.* Analogously with respect to the present claims, the Office Action's allegation regarding the inherent functional effects of Applicants' claimed invention goes astray because the Office Action is assuming what the prior art neither discloses nor renders inherent. The prior art is devoid of any language suggesting topical application to aged skin to provide an anti-ageing effect. Therefore, to say that the anti-ageing effects, including the stimulation of the growth and/or metabolism of human fibroblasts, protection of human fibroblasts from UV-A effects, protection of human keratinocytes from UV-B effects, and inhibition of melanin, are inherent, would be ignoring Applicant's explicit language of the claimed method (i.e., topically applying to the aged skin); this would be counter to the Federal

Circuit's holding in *Perricone*. Thus, Applicants submit that the claimed invention is not inherent, anticipated, nor obvious, and is patentable over the prior art.

Furthermore, as noted by the Office Action, the prior art fails to disclose a topical composition containing auxiliaries or additives as presently claimed. (Office Action at page 5). The prior art does not teach or suggest a method of treating aged skin comprising topically applying to the aged skin of a patient in need thereof a composition comprising an extract of *Buchholzia coriacea* and at least one auxiliary ingredient in an amount effective to provide anti-ageing effects. The Office Action relies upon Doi as allegedly teaching compositions useful for treating skin inflammatory conditions which comprise, or may comprise, skin additives such as antimicrobial agents. (*Id.*)

Doi relates to an antimicrobial agent having excellent antimicrobial activity against a pimple bacillus. (Doi at Abstract). Specifically, Doi teaches an antimicrobial agent comprising an extract of Coptis japonica Makino and/or an extract of Phellodendron amurense Ruprecht, and an extract of Yucca. (*Id.*)

The Office Action contends that it would have been obvious to one of ordinary skill in the art to modify the therapeutic *Buchholzia coriacea* seed and/or fruit extract preparations known in the prior art to include an additional known skin additive/auxiliary such as those claimed, including an antimicrobial agent as taught by Doi. In other words, the Office Action contends that it would have been obvious to use the teachings of Doi to arrive at Applicants' claimed invention. Doi, however, fails to make up for the deficiencies of the prior art. Doi does not teach or suggest a method of treating aged skin comprising topically applying to the aged skin of a patient in need thereof a composition comprising an extract of Buchholzia coriacea and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect. Moreover, with respect to claims 22-31, Doi is also silent as to stimulating the growth and/or metabolism or human fibroblasts, protecting human fibroblasts from UV-A effects, protecting human keratinocytes from UV-B effects, and inhibiting melanin.

Doi's composition comprises an extract of Coptis japonica Makino and/or an extract of Phellodendron amurense Ruprecht and an extract of yucca. (Doi at Abstract). That Doi additionally uses one or more conventional cosmetic adjunct ingredients in its formulation is not relevant because the prior art does not teach a composition comprising an extract of Coptis

japonica Makino and/or an extract of Phellodendron amurense Ruprecht and an extract of yucca. Therefore, without such ingredients being suggested in the extract described in the prior art, there is no rational basis on which to rely to add the auxiliary ingredients of Doi to the extracts described in the prior art. Even if such a combination were to be justified, which is not conceded here, there would be no expectation of success due to the extract of Coptis japonica Makino and/or the extract of Phellodendron amurense Ruprecht and the extract of yucca ingredients of Doi being missing from the extracts described in the prior art.

Thus, because the prior art does not recite all the limitations of the claimed invention, the Office Action has not established anticipation or *prima facie* obviousness and Applicants' invention is patentable over the prior art, and is patentable over the prior art in view of Doi (JP11322630).

Accordingly, any suggestion that the prior art disclose, teach or suggest the claimed invention would constitute improper picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited references. One would have to pick and choose among a number of broad variables to possibly arrive at Applicants' invention. *See In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention."). Indeed, picking and choosing would most definitely lead to combinations that would <u>not</u> result in the claimed invention.

The Federal Circuit has explicitly cautioned against the type of reasoning undertaken by the Examiner in this case. For example, the court in *Ruiz v. A.B. Chance Co.* stated:

> The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result - often the very definition of invention. Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole"

> assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner.

357 F.3d 1270, 1275 (Fed. Cir. 2004).

In the instant case, and as cautioned against by *Ruiz*, the Office Action has used Appellants' disclosure as a roadmap to identify unrelated elements in the cited references to arrive at the claimed invention, when none of the references even remotely suggest a method of treating aged skin comprising topically applying to the aged skin of a patient in need thereof a composition comprising an extract of *Buchholzia coriacea* and at least one auxiliary and/or additive in an amount effective to provide an anti-ageing effect. This is the epitome of "impermissible hindsight," and cannot support a *prima facie* case of obviousness. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1443 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.").

For at least the foregoing reasons, the combination of the prior art with Doi fail to disclose Applicants' invention as claimed in claim 10, and thus, claim 10 is patentable over the cited references. Accordingly, withdrawal of this rejection is respectfully requested.

For the same reasons that claim 10 is patentable, claims 12-13, 15 and newly added claims 22-31 are patentable. Withdrawal of the rejection of these claims is also respectfully requested.

CONCLUSION

It is believed that claims 10, 12-13, 15, and 22-31 are now in condition for allowance, early notice of which would be appreciated. Submitted herewith is a Request for Continued Examination, together with the appropriate fee. It is believed that no other fees are due at this time. If any additional fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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